

REMARKS / ARGUMENTS

Claims 21-47 are currently pending. The present Amendment amends claims 21, 31, 36 and 45; and cancels claims 26, 40 and 41. No new matter is added to this case by this Amendment. Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Amendments to the Claims and Support for Amendment

Claim 21 has been amended to specify (1) that *"all the lubricating agent is distributed on the tablet outer surface"*, a limitation that was recited in Claim 41 (which is now cancelled) and (2) that *"the lubricating agent is present in a range of 0.2 to 10 parts per 1000 based on a weight of lubricating agent per total weight of the tablet"*, a limitation that was recited in Claim 26 (which is now cancelled).

Claim 31 has been amended to specify that the process comprises steps of *"dry mixing the active substance and the excipients to form a mixture, provided that the lubricating agent is not included in the mixture", "applying all of the lubricating agent onto walls surrounding a cavity of a compression device" and "feeding a quantity of the mixture necessary to form a tablet into the cavity of the compression device within which the mixture is to be compressed and onto the walls of which all of the lubricating agent has been applied in advance"*. Support for this amendment can be found in Claim 40 (which is now cancelled).

Claim 31 has also been amended to specify that the process leads to a tablet *"wherein all of the lubricating agent of the tablet is distributed on an outer surface of the tablet"*, a limitation that was recited in Claim 40 (which is now cancelled) and to specify that *"the lubricating agent is present in a range of 0.2 to 10 parts per 1000 based on a weight of lubricating agent per total weight of the tablet"*. Support for this limitation can be found in the specification, for example, on page 2, lines 25-27.

Claim 45 has been amended to specify that the process comprises a step of *"spraying a lubricating agent on a surface of compression punches such that all of the lubricating agent is distributed on a tablet outer surface"*, and that the process leads to a tablet in which *"the lubricating agent is present in a range of 0.2 to 10 parts per 1000 based on a weight of lubricating agent per total weight of the tablet"*.

As mentioned above, support for such limitations can be found in Claim 40 (which is now cancelled) and in the specification, for example on page 2, lines 25-27.

Claim 36 has been amended for consistency in the language used.

Rejection under 35 U.S.C. § 103

The Examiner has rejected claims 21-47 under 35 USC § 103(a) as being obvious over U.S. Pat. No. 5,464,632 ('632) in view of U.S. Pat. No. 5,643,630 ('630). More specifically, the Examiner states that '632 discloses a directly compressible tablet comprising: a dry mixture of an active substance and excipients including a disintegrating agent, a soluble agent with binding properties, wherein the active substance is in the form of microgranules having a continuous polymer coating and wherein a lubricant can be added to the mixture before tableting. The Examiner acknowledges that '632 fails to teach adding more than half of the total lubricant present to the tablet surface, but cites '630, which discloses depositing dosed quantities of pulverized lubricants on the material contacting surfaces of pressing tools of tableting machines; the amount of lubricant actually deposited on the surface of the tablet in this technique being generally less than 0.02% (0.2 parts per 1000) based on the total weight of the tablet. According to the Examiner, it would have been obvious to one skilled in the art to deposit dosed quantities of a pulverized lubricant on the material contacting surface used to make the tablet of '632.

Applicant respectfully disagrees, and for reasons set forth below, submits that the Examiner has failed to show that the prior art references teach or suggest all of the claim limitations, as required to support a *prima facie* case of obviousness.

In particular, Applicant submits that '630 does not teach or suggest a tablet (or a method for preparing such a tablet) wherein all of the lubricating agent is distributed on the outer surface of the tablet and is present in a range of 0.2 to 10 parts per 1000 based on a weight of lubricating agent per total weight of the tablet. The '630 patent discloses that "*the amount of lubricant actually deposited on [...] the tablet is extremely small, preferably smaller than 0.02% [i.e., smaller than 0.2 parts per 1000], based upon the substance to be compressed*" (see column 2, lines 31-

34). In fact, as mentioned in the specification, the process described in the '630 patent has been developed because "*a high concentration of lubricant (0.5 to 1%) is not desirable*" (see column 1, lines 35-40) and the developed process is such that "*the lubricant quantity deposited on the [tablet] can be held to a minimum*" (see column 2, lines 23-24). Therefore, '630 teaches away from a tablet (and from a process for obtaining such a tablet) in which the lubricant is present (on the tablet outer surface) in a quantity that is higher than 0.2 parts par 1000 based on the total weight of the tablet.

Thus, Applicant respectfully submits that the prior art references, taken alone or in combination, not only fail to disclose all of the claim limitations as required to support a *prima facie* case of obviousness, but more importantly teach away from the present invention. Accordingly, Applicant respectfully requests that the rejection be removed.

CONCLUSIONS

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

In the event that there are any questions concerning this amendment, or the application in general, the Examiner is respectfully urged to telephone the undersigned attorney so that prosecution of the application may be expedited.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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By:


Brian P. O'Shaughnessy
Registration No. 32747

Customer No. 21839
703 836 6620